

REMARKS

The Office Action has been carefully studied. Claim 97 is allowed. Claims 93-117 presently appear in the application, with new claim 118 being added, and the present claims define patentable subject matter warranting their allowance. Reconsideration and early allowance are hereby respectfully solicited.

The examiner indicates that formal drawings are required in response to this Office Action. Attached hereto are three sheets of formal drawings containing Figures 1-4. Approval and entry are respectfully requested.

Claim 93 is amended and the recitation of the variant is fully supported by the specification at pages 15-16.

Claims 93-96 and 98-117 have been rejected under 35 U.S.C. 112 first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the invention as now claimed. This rejection is said to concern the sufficiency of the written description with respect to the subject matter claimed and with the examiner citing the Commissioner's Revised Interim Guidelines published 21 December 1999 at 64 F.F. 71427-71440. This rejection is indicated as being applied to the newly submitted claims for reasons of record as applied to claims 59-80, 89, 90 and 92 in paper number 13 at pages 3-4.

As stated in section 5 of the Final office action, paper number 13, filed on May 25, 2000, the examiner indicates that the question of possession of the claimed antibodies and methods employing them turns on a determination as to possession of the IGIF proteins for which the antibodies are specific. The examiner holds that the amended claims no longer require that the IGIFs be both of murine origin and closely related in structure to the exemplified murine IGIF having the sequence of SEQ ID NO:2. It is said that they are thus generic to IGIF proteins meeting the broad functional limitation of independent claim 93 and various structural or biochemical limitations recited in various combinations in the dependent claims. To the extent that the claims read on antibodies which can react with any variants, which may be structurally and functionally related IGIF homologs, but may not be mIGIF, it is the examiner's position that there is no written description of those variants in the disclosure as filed to support possession of the corresponding antibodies for reasons previously of record. This rejection is respectfully traversed.

The present invention relates to monoclonal antibodies specific to mIGIF and variants thereof which can be prepared based on the amino acid sequence of SEQ ID NO:2 disclosed in the present specification. The monoclonal antibodies specific to variants of mIGIF can be obtained by using such variants or antigenic fragments thereof as disclosed in page 16, second paragraph of the specification. Based on this disclosure, as

well as other guidance provided by the disclosure of the present specification in combination with recombinant engineering techniques at the time the present invention was made, one skilled in the relevant art can reasonably understand the present invention and obtain the monoclonal antibodies of claim 93 without undue experimentation. Thus, applicants believe that the specification as filed discloses antibodies specific to mIGIF and its variants that structurally and functionally relates to mIGIF homologs, and that the claimed invention should not be restricted to a monoclonal antibody specific to mIGIF only.

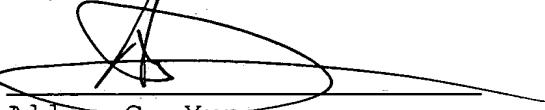
Reconsideration and withdrawal of this rejection are therefore respectfully requested.

In view of the above, the present claims comply with 35 U.S.C. §112 and define patentable subject matter warranting their allowance. Favorable consideration, entry of the amendment, and early allowance are earnestly urged.

Respectfully submitted,

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**"VERSION WITH MARKINGS TO SHOW CHANGES MADE"**

93. A monoclonal antibody which specifically recognizes (i) an interferon-gamma (IFN- $\gamma$ ) inducing protein (IGIF<sub>2</sub> or IL-18) having the following physiochemical properties or (ii) a variant thereof which has substantially the same physicochemical properties as the protein of (i) and has an amino acid sequence of SEQ ID NO:2, wherein one or more amino acids are replaced with different amino acids, one or more amino acids are added to the N- or C-terminus of SEQ ID NO:2, or one or more amino acids at the N- or C-terminus of SEQ ID NO:2 are deleted and which can recover said interferon-gamma (IFN- $\gamma$ ) inducing protein with a purity of at least 95% and in a yield of nearly 100% when used to purify said interferon-gamma (IFN- $\gamma$ ) inducing protein:

(1) Molecular weight

19,000  $\pm$  5,000 daltons on gel filtration and sodium dodecylsulfate polyacrylamide gel electrophoresis (SDS-PAGE);

(2) Isoelectric point (pI)

4.8  $\pm$  1.0 on chromatofocusing;

(3) Biological activity

Inducing the interferon- $\gamma$  production by immunocompetent cells; and

(4) Partial amino acid sequence

Possessing a part of the whole of the amino acid sequence of SEQ ID NO:2, wherein Xaa is Met or Thr.